Date Prepared	24-Sep-14
Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland Tel – 011 [353] (91) 519882 Fax – 011 [353] (91) 519873
Official Contact:	John O'Dea PhD
Proprietary or Trade Name:	EsoFLIP® ES Balloon Dilation Catheter
Common/Usual Name:	Esophageal Dilator
Classification / CFR:	PIE / CFR 876.5980 / Class 2
Device:	EsoFLIP® ES Balloon Dilation Catheter
Predicate Devices:	K983373 – B. Braun Impact Balloon Dilation Catheter K132337 – Crospon – EsoFLIP® Catheter

Device Description:
The EndoFLIP® system is an endoscopically placed device that utilizes a catheter for various indications. Crospon submitted and received 510(k) clearances for the EndoFLIP® System with a number of different catheters with different indications for use. This submission is seeking to expand the indication for use for the proposed EsoFLIP® ES catheter to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux and radiation therapy.

In all cases the catheters are to only be used with the EndoFLIP® system.

Modifications of these devices vs. Predicates:
The following is a summary of the differences between the proposed EsoFLIP® ES and the predicate Crospon EsoFLIP® ES-330 catheter, cleared under K132337.

(1) Expanded indications for use
(2) Change of the balloon material to a stiffer material for the increased inflation pressure to 2 ATM.
(3) Has diameter measurements at 16 points vs. the ES-330 (K132337) at 14 points

Indications for Use:
The EsoFLIP® ES balloon catheter is indicated for use to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux and radiation therapy.

Note: The EsoFLIP® ES catheter is to be used only with the EndoFLIP® system.

Patient Population: Patient population is patients with strictures.

Environment of Use: Hospitals and Surgery Centers

Contraindications:
The EsoFLIP® ES dilation catheter is contraindicated where:

(1) endoscopy is contraindicated,
(2) with actively bleeding varices and
(3) for diameter measurements smaller than 8 mm or greater than 20 mm

Predicate Device Comparison:

Table 1 compares the EsoFLIP® ES Balloon Dilation catheter to the predicate Crospon EsoFLIP® ES-330 (K132337) and the B. Braun Impact Balloon Dilation Catheter (K983373).

The EsoFLIP® ES dilation catheter is viewed as substantially equivalent to the predicates B. Braun Impact Balloon Dilation Catheter (K983373) and the EsoFLIP® ES-330 catheter K132337 because:

Indications – The dilation indications for use are identical to the B/ Braun Impact Balloon Dilation catheter (K983373).
Discussion – The indications for use are identical to the dilation predicate, B. Braun Impact Balloon Dilation Catheter (K983373).

Technology – The EsoFLIP® D_{est} measurement technology, construction, and design are unchanged from the EsoFLIP® ES-330 catheter, K132337, when used with the EndoFLIP® system, K120997.
Discussion – The technology is unchanged from the D_{est} measurement predicate, EndoFLIP® - K120997. The proposed EsoFLIP® ES catheter measures diameter at 16 points, like the predicate K130906, which is 2 more than the predicate ES-330 (K132337) which has 14 points.

The dilation technology of the EsoFLIP® ES catheter: maximum diameter and balloon working length, together with its use with a guidewire, is identical to the dilation predicate B. Braun Impact Balloon Dilation Catheter (K983373).

Environment of Use – The environments of use - hospital and surgery centers – are identical to the predicates.
Discussion – The environments of use are identical to the predicate B. Braun Impact Balloon Dilation Catheter (K983373) and the EsoFLIP® ES-330 (K132337).

Patient Population – The patient populations are identical, specifically indicated for patients requiring dilation of esophageal strictures.
Discussion – The patient population is unchanged and identical to the predicate B. Braun Impact Balloon Dilation Catheter (K983373).

Non-clinical Testing Summary -

Bench Testing – We performed bench testing to demonstrate that the EsoFLIP® ES balloon dilation catheter will perform within specification.

- DHF 1473 EsoFLIP® Accuracy Test
- DHF 1296 EsoFLIP® Dilation Catheter Bonds Test
- DHF 1475 EsoFLIP® Balloon Fatigue Test
- DHF 1338 EsoFLIP® Catheter Torque Tests
- DHF 1454 EsoFLIP® Balloon Burst Test
- DHF 1471 EsoFLIP® Catheter Balloon Compliance
- DHF 1469 EsoFLIP® Catheter Assembly Tests
- DHF 1514 EsoFLIP® 2 Year Shelf Life Test

The results demonstrate that the EsoFLIP® ES has met the performance specifications.

Materials –
The materials in contact with the patient are identical to the predicates, EsoFLIP® ES-330 (K132337) and balloon materials has been tested per ISO 10993-1.

In accordance with G95-1 and ISO 10993-1 the catheters are considered as

- Surface Contacting
- Mucosal membrane
- Limited duration (<24h)

They are single patient use, disposables. The materials are either identical to the Crospon the predicate EndoFLIP® catheters, K120997 or have been tested per ISO 10993-1.

Table 1 – Comparison of Proposed Device vs. Predicate

	EsoFLIP® ES-330 catheter K132337	**B. Braun Impact Balloon Dilation Catheter K983373**	**Proposed EsoFLIP® ES Catheter**
Indications for Use	Indicated for use in a clinical setting for dilating the gastro-esophageal junction of a patient with Achalasia	Indicated for use in adult and adolescent patients to dilate esophageal strictures due to: esophageal surgery, primary gastroespoh reflux and radiation therapy. Inflation pressure of 2.0 ATM	Indicated for use to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux and radiation therapy.
Environments of use	Hospital and surgery centers	Hospital and surgery centers	Hospital and surgery centers
Patient Population	Patients with Achalasia	Patients needing to dilate esophageal strictures	Patients needing to dilate esophageal strictures
Contraindications	endoscopy is contraindicated, with actively bleeding varices and with perforation of the esophagus.	Not listed in labeling	endoscopy is contraindicated, with actively bleeding varices and not suitable for diameter measurements smaller than 8mm or greater than 20mm.
Inflation Pressure	1.5 atm	2.0 atm	2.0 atm
Principle of Operation	Measurement: Provides an Estimated Diameter (D_{est}) of the balloon at 14 points along its length when inflated with saline solution. Dilation: : Balloon inflates to 30mm diameter along a working length of 80mm	Measurement: No measurements. Dilation: Balloon inflation range from 16 to 25 mm	Measurement: Provides an Estimated Diameter (Dest) of the balloon at 16 points along its length when inflated with saline solution. Dilation: Balloon inflates to 20mm diameter along a working length of 80mm

	EsoFLIP® ES-330 catheter K132337	**B. Braun Impact Balloon Dilation Catheter K983373**	**Proposed EsoFLIP® ES Catheter**
Materials used / Biocompatibility	Balloon and shaft material Pebax 7233 SA01 Tip - Pebax 2533 SA01 All materials have passed biocompatibility tests in accordance with ISO 10993-1 (K120997)	Not disclosed.	Balloon – Nylon 12 Shaft and Tip - Pebax 2533 SA01 Identical material to predicate Crospon EsoFLIP® catheter (K132337)
Biocompatibility	All materials have passed biocompatibility tests in accordance with ISO 10993-1 (K120997)	Not disclosed	Identical materials to predicate Crospon EsoFLIP® catheter (K132337) ISO 10993-1 testing for Nylon 12
Compatibility With The Environment And Other Devices	Only operates with EndoFLIP® system	Not disclosed.	Only operates with EndoFLIP® system
Sterility	Accessories are supplied non-sterile, and are single patient use, disposable	Accessories are supplied non-sterile, and are single patient use, disposable	Accessories are supplied non-sterile, and are single patient use, disposable
Performance	Range: 8 to 30 mm Resolution: 0.1 mm Accuracy: ± 1mm (at 95% confidence) rounded to nearest integer	No measurement function	Range: 8 to 20 mm Resolution: 0.1 mm. (Identical to K132337) Accuracy: ± 1mm (at 95% confidence) rounded to nearest integer. (Identical to K132337)

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device does not raise any new safety concerns compared to the predicates.